

22 MAR 31 A9 :03

SENATE
S. No. 2512



Introduced by Senator Francis "Tol" N. Tolentino

AN ACT
REGULATING PHARMACEUTICAL OUTLETS ENGAGED IN THE ONLINE SALE OF PHARMACEUTICAL PRODUCTS AND THOSE DISPENSING ONLINE PHARMACY SERVICES, AMENDING FOR THE PURPOSE REPUBLIC ACT NO. 10918, OTHERWISE KNOWN AS THE "PHILIPPINE PHARMACY ACT"

EXPLANATORY NOTE

The 1987 Constitution enjoins the State to protect and promote the right to health of every Filipino by instilling health consciousness among them,¹ and adopting an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health, and other social services available to all at affordable cost.²

On 11 June 2019, the Food and Drug Administration (FDA) issued FDA Advisory No. 2019-154, entitled "*Internet Sales and Access to Safe Medicine*," reminding the public that prevalent laws, rules, and regulations do not allow the online selling of medicines while encouraging them to purchase medicines only from licensed pharmacies, thus:

"In the Philippines, online selling of medicines is NOT permitted pursuant to existing laws, rules and regulations. Currently, FDA only allows online ordering services provided that the seller has an existing FDA-licensed Pharmacy or Botika

¹ Section 15, Article II of the 1987 Constitution.

² *Id.*, Section 11, Article XIII.

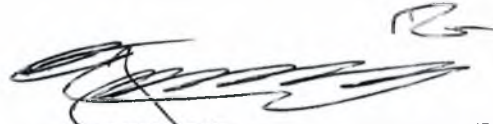
with physical address. Online ordering services are additional activities of a Pharmacy or Botika subject for approval of FDA.”

Contrary to the said FDA Advisory, Section 5(dd) of Republic Act No. 10918, (R.A. No. 10918), otherwise known as the “Philippine Pharmacy Act,” recognizes online pharmacy services and defines such as “pharmaceutical services of a duly licensed pharmaceutical outlet done over the internet.” Section 45(p) of R.A. No. 10918 penalizes the operation of an unlicensed pharmaceutical outlet rendering online pharmacy services.

Despite the enactment of R.A. No. 10918, the FDA has yet to issue detailed guidelines on the online sale of pharmaceutical drugs and the operation of online pharmacies or e-pharmacies. Until then, unscrupulous sellers will continue to sell counterfeit, adulterated, or unapproved pharmaceutical drugs to the prejudice of the public.

Given the proliferation of online e-commerce platforms and their ease of access and convenience especially during the pandemic, this bill seeks to regulate *(a)* the online sale of pharmaceutical drugs and *(b)* the operation of e-pharmacies.

In view of the foregoing, the approval of this measure is earnestly sought.



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10918, OTHERWISE KNOWN AS THE "PHILIPPINE PHARMACY ACT"

Be it enacted by the Senate and the House of Representatives of the Philippines in Congress assembled:

1 SEC. 1. Section 5 of Republic Act No. 10918, otherwise known as the "*Philippine*
2 *Pharmacy Act*," is hereby amended to read, thus:

3 "SECTION 5. *Definition of Terms.* — As used in this Act: x x x

4 **(XX) ONLINE PHARMACY OR E-PHARMACY REFERS TO A**
5 **MODE OF PHARMACY SERVICES THAT UTILIZES INFORMATION**
6 **TECHNOLOGY OR ONLINE MODE OF COMMUNICATION TO**
7 **BETTER SERVE PATIENTS BY PROVIDING MORE CONVENIENT**
8 **ACCESS TO PHARMACY SERVICES. THIS MODE OF SERVICE**
9 **SHOULD BE PROVIDED BY A PHARMACY THAT IS DULY-**
10 **LICENSED BY THE FDA THROUGH A SECURED ONLINE**
11 **PLATFORM;**

12 **(YY) ONLINE E-COMMERCE PLATFORM REFERS TO A**
13 **NATURAL OR JURIDICAL PERSON THAT SOLICITS THE**
14 **PURCHASE OF DIGITAL PRODUCTS THROUGH DIGITAL**
15 **PLATFORMS AND MARKETPLACES WHOSE BUSINESS IS TO**

1 CONNECT ONLINE BUYERS AND ONLINE SELLERS,
2 FACILITATING SALES OF PRODUCTS, GOODS, AND SERVICES
3 THROUGH THE INTERNET WITH THE PRESENCE AND USE OF
4 MONETARY TRANSACTIONS.”

5 SEC. 2. A new Article VIII is hereby inserted to R.A. No. 10918 and succeeding
6 Sections are renumbered accordingly to read, thus:

7 **“ARTICLE VIII**

8 **ONLINE PHARMACY (E-PHARMACY)**

9 **SECTION 47. *LICENSE TO OPERATE AS ONLINE PHARMACY (E-***
10 ***PHARMACY).* - PHARMACEUTICAL OUTLETS ENGAGED IN THE SALE**
11 **OF PHARMACEUTICAL PRODUCTS, WHETHER AS AN ADDITIONAL**
12 **ACTIVITY OR AS A PURE E-PHARMACY WITHOUT A PHYSICAL STORE**
13 **FOR DISPENSING MEDICINES AND MEDICAL DEVICES, SHALL**
14 **REGISTER WITH THE FDA AND SECURE THE APPROPRIATE LICENSE**
15 **FOR THIS PURPOSE.**

16 **SECTION 48. *LICENSED PHARMACIST REQUIREMENT.* - ALL**
17 **PHARMACEUTICAL OUTLETS ENGAGED IN THE ONLINE SALE OF**
18 **PHARMACEUTICAL PRODUCTS SHALL DESIGNATE A LICENSED**
19 **PHARMACIST WHO SHALL BE RESPONSIBLE AND ACCOUNTABLE FOR**
20 **COMPLIANCE WITH LAWS AND FDA RULES AND REGULATIONS**
21 **PERTAINING TO PRODUCT SAFETY, EFFICACY, AND QUALITY.**

22 **SECTION 49. *GUIDELINES ON THE APPLICATION FOR A***
23 ***LICENSE TO OPERATE.* - ALL PHARMACEUTICAL OUTLETS ENGAGED**
24 **IN ONLINE SALE OF PHARMACEUTICAL PRODUCTS, WHETHER AS AN**
25 **ADDITIONAL ACTIVITY OR AS A PURE E-PHARMACY, SHALL BE**
26 **SUBJECT TO MONITORING AND REGULAR INSPECTION BY THE FDA.**
27 **FOR THIS PURPOSE, THE FDA, IN COOPERATION WITH**
28 **APPROPRIATE GOVERNMENT AGENCIES, SHALL PROMULGATE**
29 **GUIDELINES ON THE LICENSING AND COMPLIANCE REQUIREMENTS**
30 **FOR PHARMACEUTICAL OUTLETS ENGAGED IN THE ONLINE SALE OF**
31 **PHARMACEUTICAL PRODUCTS AND THOSE DISPENSING ONLINE**
32 **PHARMACY SERVICES.”**

1 SEC. 3. *Separability Clause.* — If any clause, provision, paragraph, or part
2 hereof shall be declared unconstitutional or invalid, such declaration shall not affect,
3 invalidate, or impair the other provisions otherwise valid and effective.

4 SEC. 4. *Repealing Clause.* — All other laws, presidential decrees, executive
5 orders, and other administrative issuances or parts thereof which are contrary to or
6 inconsistent with the provisions of this Act are hereby repealed, amended, or modified
7 accordingly.

8 SEC. 5. *Effectivity.* — This Act shall take effect fifteen (15) days after its
9 publication in the *Official Gazette* or in a newspaper of general circulation.

Approved,